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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 2003N–0285]

Summaries of Medical and Clinical Pharmacology Reviews of Pediatric Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of summaries of the medical and clinical pharmacology reviews of pediatric studies submitted in supplements for Hycamtin (topotecan), Pulmicort (budesonide), Temodar (temozolomide), Effexor (venlafaxine), Ditropan (oxybutynin), Flonase (fluticasone), Allegra (fexofenadine), Duragesic (fentanyl), and Monopril (fosinopril). The summaries are being made available consistent with the Best Pharmaceuticals for Children Act (BPCA). For all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of the pediatric studies conducted for the supplement.

ADDRESSES: The summaries are available for public examination between 9 a.m. and 4 p.m., Monday through Friday, in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the summaries to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Please specify by product name which summary or

summaries you are requesting. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries.

FOR FURTHER INFORMATION CONTACT: Terrie L. Crescenzi, Center for Drug Evaluation and Research (HFD–950), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–7337, CrescenziT@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of summaries of the medical and clinical pharmacology reviews of pediatric studies conducted for Hycamtin (topotecan), Pulmicort (budesonide), Temodar (temozolomide), Effexor (venlafaxine), Ditropan (oxybutynin), Flonase (fluticasone), Allegra (fexofenadine), Duragesic (fentanyl), and Monopril (fosinopril). The summaries are being made available consistent with section 9 of the BPCA (Public Law 107–109). Enacted on January 4, 2002, the BPCA reauthorizes, with certain important changes, the pediatric exclusivity program described in section 505A of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355a). Section 505A of the act permits certain applications to obtain 6 months of marketing exclusivity if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population.

One of the provisions the BPCA added to the pediatric exclusivity program pertains to the dissemination of pediatric information. Specifically, for all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of pediatric studies conducted for the supplement (21

U.S.C. 355a(m)(1)). The summaries are to be made available not later than 180 days after the report on the pediatric study is submitted to FDA (21 U.S.C. 355a(m)(1)). Consistent with this provision of the BPCA, FDA has posted on the Internet (*http://www.fda.gov/cder/pediatric/index.htm*) summaries of the medical and clinical pharmacology reviews of the pediatric studies submitted in supplements for Hycamtin (topotecan), Pulmicort (budesonide), Temodar (temozolomide), Effexor (venlafaxine), Ditropan (oxybutynin), Flonase (fluticasone), Allegra (fexofenadine), Duragesic (fentanyl), and Monopril (fosinopril). Copies are also available for public examination in the Division of Dockets Management or may be requested by mail (see **ADDRESSES**).

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cder/pediatric/index.htm.*

Dated: 6/27/03
June 27, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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